Clinical Data

JUN 17 2003

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K030528

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC Iron Reagent Kit and ATAC TIBC Column Kit are intended for the quantitative determination of total iron and total iron binding capacity in serum. Total iron results are used for the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. Total iron binding capacity measurements are used for the diagnosis and treatment of anemia.

The ATAC Iron Reagent measures total serum iron by stripping it from the transferrin in a low pH reagent buffer, oxidizing it to ferric ions and binding it with Ferrozine. The resulting increase in absorbance at 546 nm is proportional to the iron concentration in the sample. The ATAC TIBC Column Kit is used to pretreat serum specimens prior analysis. The iron in the saturating reagent ensures that all available iron binding sites in the serum specimen are saturated with iron. The filtrate is assayed with an iron reagent after removing the unbound iron form the sample mixture by passing it through an alumina column. The maximum amount of iron bound in the specimen is a measure of its transferrin concentration.

The ATAC Iron Reagent Kit, which contains the Iron Calibrator (500 µg/dL), is substantially equivalent to the Beckman Synchron Systems Iron Reagent, product 467910 and the Beckman Synchron Systems Fe/IBCT Calibrator, product 442772. The ATAC TIBC Column Kit and ATAC 8000 TIBC application is substantially equivalent to the Beckman Synchron Systems Total Iron Binding Capacity (IBCT) Column Kit, product no. 465976 (Beckman Coulter, Inc. of Brea, CA).

The effectiveness of ATAC Total Iron Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown in the following studies.

The recovery of iron using the ATAC Total Iron Reagent is linear from 25 to 500 µg/dL, as shown by the recovery of linearity standards that span the usable range. Regression statistics that compare standard recoveries to standard values yield a standard error estimate of 3.1 µg/dL.

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Iron Recoveries in µg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	67	1.5	2.2%	2.9	4.3%
Serum 2	60	177	1.9	1.1%	4.4	2.5%
Serum 3	60	282	4.3	1.5%	8.5	3.0%

Serum specimens, collected from adult patients, were assayed for iron using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

ATAC 8000 = 8.8 µg/dL + 0.969 x Competitive Reagent
$s_{y.x}$ = 3.0 µg/dL n = 58 range = 31 - 165 µg/dL

The 14 day onboard reagent stability and 7 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, estimates of the total imprecision of iron recoveries over the test periods are less than the greater of 4 µg/dL or 4%.

The effectiveness of ATAC TIBC Column Kit is shown in the following studies with the ATAC Total Iron Reagent Kit on the ATAC 8000 Random Access Chemistry System.

TIBC recoveries using the ATAC TIBC Column Kit are linear from 125 to 500 µg/dL, as shown by the recovery of diluted serum pools that span the usable range. Regression statistics that compare standard recoveries to dilution factors yield an estimate of standard error of regression of 6 µg/dL.

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of TIBC Recoveries in µg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	247	4.5	1.8%	4.9	2.0%
Serum 2	60	391	7.6	1.9%	10.7	2.8%

Serum specimens, collected from adult patients, were assayed for iron using the ATAC 8000 TIBC Application and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

ATAC 8000 = 8.2 µg/dL + 0.964 x Competitive Reagent
$s_{y.x}$ = 7.8 µg/dL n = 55 range = 237 - 470 µg/dL

Wynn Stocking
Manager of Regulatory Affairs
Elan, Brea California

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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Mr. Wynn Stocking
Manager, Regulatory Affairs
Clinical Data
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Re: k030528
Trade/Device Name: ATAC Iron Reagent, Iron Calibrator and TIBC Column Kit
Regulation Number: 21 CFR 862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I
Product Code: JIY; JMO
Dated: June 3, 2003
Received: June 4, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030528

Device Name: ATAC Iron Reagent, Iron Calibrator and TIBC Column Kit

Indications for Use:

The ATAC Iron Reagent Kit, which contains both reagent and calibrator, is intended for use with the ATAC 8000 Random Access Chemistry System as a system for the quantitative determination of total iron in serum. The ATAC TIBC Column Kit, which is marketed with generic labeling and an ATAC 8000 Application Sheet, is intended for use with the ATAC Iron Reagent Kit and other iron reagents for the quantitative determination of total iron binding capacity in serum.

Total iron results are used for the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. Total iron binding capacity measurements are used for the diagnosis and treatment of anemia.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030528

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)